VACANCY MEDIOR POSITION

Product Development & Outsourcing Manager

for Medical Devices

THE COMPANY

LiGalli is a fast-growing company, located in the Netherlands, developing a medical device for drug-delivery and diagnostics for women. The company revolutionizes the way women are being treated, monitored, and diagnosed by providing a unique product. This 'MedRing as a Platform' consists of a vaginal device for drug delivery, a smartphone application and a cloud environment and is suitable for a wide range of compounds and a basis for diagnostic applications.

LiGalli has a flat organization structure with an experienced, driven, and ambitious team (of which more than 50% is female – something we believe worth mentioning when developing a product for women's health). We believe in an informal work culture, where we leverage on each other's experience, know-how and input. We consider team work to be essential for success, not only between colleagues in our team, but also with our 'indirect colleagues' i.e. representatives from partners.

To achieve our 'big hairy audacious goal' we have surrounded ourselves with a wide range of partners (for research, development, clinical trials, regulatory affairs and production). We are developing the product in close cooperation with our partners where, next to the internal activities, we act as the orchestrator in the middle, to achieve our goals. Within R&D this means - in practice - that we establish requirements, lead design decisions, manage and support the development process and verify the outcome, but the engineering is outsourced to our partners.

YOUR JOB

As the Product Development & Outsourcing Manager at LiGalli, you will work directly with the CTO and Product Usability & User Experience Manager to support and/or take over part of their (technical) activities:

- Support the partner management activities for the outsourced hardware and software development (e.g. establish and provide design inputs for development partners, review design outputs, ensure proper execution of design verification and validation activities and support the establishment of the Design History File (DHF) within the QMS).
- Support the partner management activities for the outsourced manufacturing processes (e.g. technical support of the procurement team with for supplier selection and contracts, support the NPI processes of the manufacturing partners to set up and validate (IQ, OQ & PQ) the production process.
- Support (or lead) internal development projects outside of the responsibility of our partners.

We are looking for a passionate colleague with a technical background (i.e. industrial design engineering, integrated product design, mechanical engineering), who is more of a 'generalist' than a 'topic expert' and - within the field of product development and production – also has an interest to be involved in operational/ management activities. Your day-to-day activities will be a combination of working independently on projects in which you take the lead but also execute supporting tasks under the direction of the CTO (or others).

Working in a small, fast-growing, organization requires you to take ownership of your tasks and responsibilities assigned to you, take up tasks with a pro-active attitude and being able to work both independently and in close cooperation with others. Being flexible, resilient, and able to deal with uncertainties is needed for the stage our company is in.

Within LiGalli you will have the opportunity to gain experience within a broad scope of activities, as your involvement will not be limited to supporting the management of hardware and software development, but also extend to supplier selection, evaluation and contracting processes, design transfer and production setup, regulatory and quality management documentation, and business aspects of the organization.

From a personality perspective we are looking for a colleague who is a hands-on team player as well as independent in execution, ambitious and eager to learn, knowledgeable and smart, organized and methodological, and who takes pride in delivering high quality work.

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The vacancy is for a full-time medior position (32-40 hours per week).

WE OFFER
- An exciting, open work environment where new challenges are faced every day.
- The opportunity to make a difference for Women's Health and to ensure we deliver high-quality products.
- Personal and professional growth and development opportunities.
- A competitive salary.
- A nicely situated office at the BioPartner Science Park in Leiden (close to Leiden CS and the A44).

YOU HAVE / YOU ARE
- ✓ A technical degree; Higher Professional Education ("HBO") or University.
- ✓ [Required] Strong analytical skills and excellent command in English, both verbal and in writing.
- ✓ [Required] Prior work experience (3-5 years) within product development, preferable within medical device development.
- ✓ [Required] Experience with methodological development processes, establishing requirements, performing risk management, verification and validation activities and technical documentation.
- ✓ [Preferred] Familiarity with medical device regulations and standards (i.e. MDD/MDR, ISO13485) and experience with establishing design and development records.
- ✓ [Preferred] Tech savvy with good computer skills.
- ✓ Ability to work independently as well as part of a team.
- ✓ Ability to build long term relationships with partners.
- ✓ Ambitious and eager to learn.
- ✓ Organized with eye for detail, pragmatic and result oriented.
- ✓ [Beneficial] Affection with healthcare, technology and/or drug development.

JOIN OUR TEAM! Send your application & CV to **info@ligalli.health** to apply.

Unsolicited services or offers from recruitment agencies or intermediaries will not be responded to.